

MAR 29 2002

**Special 510(k) Summary: Design Modification of the Dyax Lag Screw  
to the Gamma 3 Lag Screw**

**Submission Information**

Name and Address of the Sponsor of the 510(k) Submission: Howmedica Osteonics Corp  
59 Route 17  
Allendale, NJ 07401-1677

Contact Person: Karen Ariemma  
Regulatory Affairs Specialist

Date of Summary Preparation: February 27, 2002

**Device Identification**

Proprietary Name: Gamma 3 Lag Screw  
Common Name: Intramedullary Nail  
Classification Name and Reference: Intramedullary Fixation Rod, 21 CFR §888.3020

This Special 510(k) submission is intended to address a design modification of the Dyax Lag Screw to create the subject device which is referred to as the Gamma 3 Lag Screw. The design modification involves changes to the thread diameter; thread radius and cutting flute design. The subject device is intended to be used with both the Long Length Dyax Nail and the Trochanteric Dyax Nail. The design modification involves changes to the thread diameter; thread radius and cutting flute design

There is no change in intended use for the modified device when compared to the previously cleared product. The subject Gamma 3 Lag Screws are substantially equivalent to the existing design of Dyax Nail Lag Screw that were determined substantially equivalent via the 510(k) process.

K020677  
page 1 of 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 29 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Karen Ariemma  
Regulatory Affairs Specialist  
Howmedica Osteonics Corporation  
59 Route 17  
Allendale, New Jersey 07401-1677

Re: K020677

Trade/Device Name: Gamma 3 Lag Screw  
Regulation Number: 888.3020  
Regulation Name: Intramedullary fixation rod  
Regulatory Class: II  
Product Code: HSB  
Dated: February 27, 2002  
Received: March 1, 2002

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

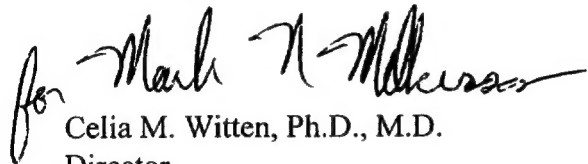
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Karen Ariemma

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Mark N. Witten

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K 020677

Device Name: Gamma 3 Lag Screw

Indications For Use:

The Gamma 3 Lag Screw is intended to be used with both the Long Length Dyax Nail and the Trochanteric Dyax Nail.

Intended Use for the Long Length Dyax Nail

The product is intended to be used in fixation of femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intracondylar notch. Fracture types include basilar neck, intertrochanteric, subtrochanteric fractures and femoral shaft fractures. These femoral fractures may occur as a result of trauma, non-union, mal-union, pathological fractures, and impending pathological fractures.

Intended Use for the Trochanteric Dyax Nail

The product is intended for use in stabilizing various types of intertrochanteric fractures of the femur.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

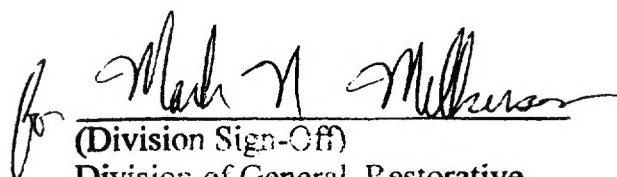
Prescription Use ☒

OR

Over-The-Counter Use ☐

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K 020677